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JOHN P. HEHMAN
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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO

UNITED STATES EX REL. GEORGE ARNOLD, LAURA BATSCHE, RANDALL BREWER, SANDRA DENNIS, CAROLYN DOTSON, JOANN FRAZIER, DONNA GOOD, KELLY HENNESSY, TAMMY JONES, TIMOTHY MARSHALL, JULIE MARTIN, TERESA MCMILLAN, JOETTA NAFE, MARY RAVENSCRAFT, DONNA RISTER, DOROTHY ROSE, CAROL ROSS, JOSEPH SCHIMMEL, DANA SETTERS, DANIEL WEBBER, and THE ESTATE OF WILLIAM HAYES

Plaintiffs,

vs.

ALPHATEC SPINE, INC.
C/O EBUN S GARNER
5818 EL CAMINO REAL
CARLSBAD, CA 92008

AND

ALPHATEC HOLDINGS, INC.
C/O
CORPORATION SERVICE COMPANY
2711 CENTERVILLE RD SUITE 400
WILMINGTON, DE 19808

AND

PARCELL LABORATORIES, LLC
C/O
UNITED STATES CORPORATION AGENTS, INC.
1521 CONCORD PIKE STE 301
WILMINGTON, DE 19803

AND

CASE NO. 1:13CV586

Judge J. BLACK

QUI TAM COMPLAINT

FILED UNDER SEAL

JURY DEMAND

WEST CHESTER HOSPITAL, LLC :
C/O GH&R BUSINESS SERVICES, INC. :
511 WALNUT STREET :
1900 FIFTH THIRD CENTER :
CINCINNATI, OH 45202 :

AND

UC HEALTH :
C/O GH&R BUSINESS SERVICES, INC. :
511 WALNUT STREET :
1900 FIFTH THIRD CENTER :
CINCINNATI, OH 45202 :

AND

DR. ATIQ ABUBAKAR DURRANI :
6905 BURLINGTON PIKE :
FLORENCE, KY 41042

AND

DR. NEAL SHANTI
6905 BURLINGTON PIKE :
FLORENCE, KY 41042

AND

THE CENTER FOR ADVNACED SPINE :
TECHNOLOGIES :
C/O CT CORPORATION :
1300 EAST 9TH STREET SUITE 1010 :
CLEVELAND, OH 44114 :

AND

JOURNEY LITE OF CINCINNATI, LLC :
C/O :
THE CORPORATION TRUST COMPANY :
CORPORATION TRUST CENTER :
1209 ORANGE ST :
WILMINGTON, DE 19801 :

AND

BARIATRIC PARTNERS, INC. :

C/O
CORPORATION SERVICE COMPANY :
2711 CENTERVILLE RD STE 400 :
WILMINGTON, DE 19808 :

Defendants. :

Plaintiffs/Relators bring this qui tam action in the name of the United States of America, by and through undersigned counsel Eric C. Deters and allege as follows.

THIS CLAIM IS TO BE FILED UNDER SEAL AND HAS BEEN SEPARATELY SERVED UPON THE GOVERNMENT AS REQUIRED BY THE FALSE CLAIMS ACT, 21 U.S.C. § 3729 ET SEQ., WITH WAIVER OF SERVICE UPON DEFENDANTS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 4(d)(4).

SUMMARY

1. This matter concerns a fraudulent scheme whereby Defendants reaped significant profits by 1) using patients as research subjects without their knowledge, 2) charging the patients and their insurers for implants that were not used in compliance with the FDA approval process and which uses were not disclosed to the patients as necessary to obtain informed consent, 3) knowingly concealing the charges for the implants, not reporting to the patient or insurer that the devices were not approved for such use, not obtaining precertification for such use, not obtaining informed consent for experimental use, and 4) knowingly performing medically unnecessary surgeries while representing them as medically necessary.

2. There were several goals of this scheme including but not limited to 1) conducting unapproved research on unknowing patients to expand and obtain FDA approval for the product PureGen and products containing the same active ingredient (collectively "PureGen"); and 2) boosting sales of PureGen through illegal off label promotion; illegal kickback agreements which may have involved patent options and license, direct

payments, compensation through doctor owned distributorships or other business relationships, and splitting payments made by Medicare, Medicaid, and all other government benefits programs related to health (hereinafter "Medicare" unless otherwise stated). These goals were accomplished in part or in whole by the United States and its taxpayers through the false claims submitted by the participants in the scheme.

3. This action is filed on behalf of the United States of America by the Relators to recover treble damages, civil penalties, disgorgement of gross receipts or profits, the imposition of a constructive trust, attorneys' fees, expenses, exemplary damages and all other applicable remedies for the payments made on false claims presented to Medicare.

4. The Defendants have engaged in a scheme involving civil conspiracy, fraud, material misrepresentation, deceit, and extreme and outrageous conduct intentionally directed at each of the patients. In furtherance of their scheme to defraud, the Defendants have violated and/or caused others to violate several statutes, regulations, and other Federal requirements including but not limited to:

   a. The False Claims Act 31 U.S.C. § 3729, et seq.;
   b. 42 C.F.R. §482.13, codifying the Patient's Right to Informed Consent;
   c. 42 C.F.R. §482.51, covering the informed consent of surgical patients;
   d. 45 C.F.R. Part 46, et seq., specifically 45 C.F.R. §46.122, covering the conducting of medical research on human subjects with the support of federal funds, known as the "Common Rule";
   e. 18 U.S.C. §1035, covering the criminal act of making "False Statements Relating to Health Care Matters" involving any health care benefit program, public or private;

f. 18 U.S.C. §1347 of the Criminal Code covering "Health Care Fraud" involving any health care benefit program, public or private;

g. 18 U.S.C. §§ 1341, 1343, 1956, 1957, and 2314 covering "Mail Fraud", "Wire Fraud", "Money Laundering", "Use of Dirty Money", and "Travel to Effect the Scheme", to effectuate the fraudulent scheme; and

h. The violation of the warning letter from the FDA dated June 23, 2011 warning against promoting and marketing PureGen without FDA approval; and for violating the Food Drug and Cosmetic Act, 21 U.S.C. § 351, et seq., by marketing a device without premarket approval, 510k clearance, meeting the humanitarian device exception, exemption from the Act, or other qualification to market the device; for violating the Public Health Service Act 42 U.S.C. §201, et seq., specifically § 262(a) and (i), and related federal regulations, specifically 21 C.F.R. 1271.10(a)(4)(ii)(b); for violating the Food Drug and Cosmetic Act 21 U.S.C. §351, et seq., specifically § 355(a) and (i), and 21 C.F.R. 312; and the Public Health Service Act 42 U.S.C. 262, specifically § 262(a) and (i).

5. This cause of action is brought by Relators pursuant to the *qui tam* provisions of 31 U.S.C. §3729, et seq., and other applicable rules and law.

PARTIES

6. Relators are citizens and residents of the State of Ohio or the Commonwealth of Kentucky, are the original sources of the information on which the allegations are based, have direct and independent knowledge on which the allegations are based, and have voluntarily provided the information to the government.

7. Pursuant to 31 U.S.C. § 3732(b), this action may be joined by the State of Ohio, the

Commonwealth of Kentucky, and any other state or local authorities should it discover that the fraudulent, conspiratorial activities have damaged those entities due to payments obtained by false claims under their programs, including Medicaid.

8. Defendant Alphatec Spine, Inc. is a corporation under the laws of California, and jointly developed and distributes PureGen in the State of Ohio. The agent for service of process (service waived pursuant to R.Civ.Pro. 4(d)(4) and 4(i)) is Ebun S Garner, 5818 El Camino Real, Carlsbad, CA 92008.

9. Defendant Alphatec Holdings, Inc. is a holding corporation formed under the laws of Delaware with no operations separate from the holding of other companies which owns Alphatec Spine, Inc. The agent for service of process (service waived pursuant to R.Civ.Pro. 4(d)(4) and 4(i)) is Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, DE 19808.

10. Defendant Parcell Laboratories, LLC is organized under the laws of Delaware and jointly developed PureGen. The agent for service of process (service waived pursuant to R.Civ.Pro. 4(d)(4) and 4(i)) is United States Corporation Agents, Inc., 1521 Concord Pike, Ste 301, Wilmington, DE 19803.

11. Defendant West Chester Hospital, LLC is organized under the laws of Ohio and provides hospital services in Ohio including location, support staff, and billing services to physicians and employing physicians. The agent for service of process (service waived pursuant to R.Civ.Pro. 4(d)(4) and 4(i)) is GH&R Business Services, Inc., 511 Walnut Street, 1900 Fifth Third Center, Cincinnati, OH 45202.

12. Defendant UC Health is organized as a non profit under the laws of Ohio, owns West Chester Hospital, and provides billing services to West Chester Hospital. The agent for

service of process (service waived pursuant to R.Civ.Pro. 4(d)(4) and 4(i)) is GH&R Business Services, Inc., 511 Walnut Street, 1900 Fifth Third Center, Cincinnati, OH 45202.

13. Defendants Dr. Durrani and Dr. Shanit are/were licensed to practice medicine in the State of Ohio and the Commonwealth of Kentucky, has been indicted for Medicare fraud related to unnecessary surgeries, and performed the surgeries on Relators involving PureGen. Dr. Durrani and Dr. Shanti can be served (service waived pursuant to R.Civ.Pro. 4(d)(4) and 4(i)) at 6905 Burlington Pike, Florence, KY 41042.

14. Defendant the Center for Advanced Spine Technologies, Inc. is a corporation under the laws of Ohio and provides medical offices and is owned in whole or in part by Defendant Dr. Durrani. The agent for service of process (service waived pursuant to R.Civ.Pro. 4(d)(4) and 4(i)) is CT Corporation, 1300 East 9th Street, Suite 1010, Cleveland, OH 44114.

15. Defendant JourneyLite of Cincinnati is a corporation organized under the laws of Delaware, and provides medical facilities and billing support to physicians, including Durrani, in the State of Ohio. The agent for service of process (service waived pursuant to R.Civ.Pro. 4(d)(4) and 4(i)) for JourneyLite is the Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.

16. Defendant Bariatric Partners, Inc. is a corporation under the laws of Delaware, is the parent company of Defendant JourneyLite of Cincinnati, and the agent for service of process (service waived pursuant to R.Civ.Pro. 4(d)(4) and 4(i)) is Corporate Service Company, 2711 Centerville Road STE 400, Wilmington, DE 19808.

JURISDICTION AND VENUE

17. Jurisdiction and Venue are proper in this Court pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732. The causes of action alleged herein arose out of actions and/or omissions that occurred or accrued, in part, in Hamilton County, Ohio and/or Butler County, Ohio which are within the judicial district of this Court.

FACTUAL BACKGROUND

18. The factual allegations are made with the requisite specificity required by Rule 8 and Rule 9(b) as limited by the yet-to-be-discovered actions and/or omissions by the Defendants and any unknown conspirators.

19. Alphatec and Parcell co-developed the product "PureGen", and both expected PureGen would be initially limited in application.

20. Puregen is produced and distributed by Alphatec Spine, LLC, a division of Alphatec Holdings, Inc.

21. Puregen was entered into clinical trials by Alpatec on or around February 9, 2011 which were scheduled to last until September of 2013.

22. The clinical trial required:

   a. Inclusion:

      i. Age over 50

      ii. Side-by-side use of PureGen and Autologous bone in the same patient for radiographic comparison

      iii. Symptomatic lumbar degenerative disc disease in up to 2 contiguous levels between L1 and S1

      iv. Subjects with back and/or leg pain indicated for posterior stabilization with or without decompression at any level and posteriolateral fusion

v. Unresponsive to conservative treatment for at least 6 months

vi. Radiographic evidence of primary diagnosis

b. Exclusion:

i. No healthy volunteers permitted

ii. More than two levels requiring posteriolateral fusion (PLF)

iii. Spondyliosis greater than Grade I

iv. Prior failed fusion surgery at any lumbar level(s)

v. Systemic or local infection in the disc or cervical spine, past or present

vi. Active systemic disease

vii. Osteoporosis, Osteomalacia, or other metabolic bone disease that would significantly inhibit bone healing

viii. Use of other bone graft, Bone Morpohogenic Protein (BMP), or bone graft substitutes in addition to or in place of those products specified

ix. BMI greater than 40

x. Use of post operative spinal cord stimulator

xi. Known or suspected history of alcohol and/or drug abuse

xii. Involved in pending litigation or worker's compensation related to the spine

xiii. Pregnant or planning to become pregnant during the course of the study

xiv. Insulin-dependent diabetes mellitus

xv. Life expectancy less than duration of study

xvi. Any significant psychological disturbance that could impair consent process or ability to complete self-assessment questionnaires

xvii. Undergoing chemotherapy or radiation treatment, or chronic use of oral or injected steroids or prolonged use of non-steroidal anti-inflammatory drugs

xviii. Known history of hypersensitivity or anaphylactic reaction to dimethyl sulfoxide (DMSO)

23. Alphatec and Parcell saw this limited approval for clinical trials as an opportunity to market PureGen without premarket approval, 510K clearance, an exception to the Food Drug and Cosmetic Act, meeting the humanitarian device exception, investigational new drug (IND) application, or other permission to market PureGen, all in violation of the Food Drug and Cosmetic Act.

24. Motivated by greed and a desire to gain a competitive advantage in the marketplace, Alphatec and Parcell began a course of conduct designed to expand the application of PureGen by end users in excess of the approved clinical trial of PureGen. This course of conduct utilized fraud, false statements, material misrepresentation, and deceit in order to broaden the sales of PureGen beyond that which the usual acceptance within the scientific community or regulatory approval would otherwise allow.

25. According to the Public Health Service Act, a valid biologics license is also required to introduce a biologics device to the market.

26. Alphatec Spine did not acquire a valid biologics license to enter a biological product into interstate commerce, in violation of 21 U.S.C. 355(a); 42 U.S.C. 262(a).

27. The FDA responded quickly to the off label marketing of the device PureGen by warning that PureGen was not the subject of an IND application nor a valid biologics license with a letter dated June 23, 2011.

a. Defendants knew or should have known that Puregen was not safe for human use.

b. Defendants knew or should have known that Puregen was not approved by the Food and Drug Administration for any purpose.

c. Defendants knew or should have known that marketing the PureGen product following the FDA warning was illegal.

28. Alphatec and Parcell responded to this letter by continuing to market PureGen off label until Alphatec acknowledged the letter in or around February 2013, almost two years after receiving the letter, by stating it disagrees with the FDA's classification of PureGen as anything other than a tissue product – despite the clinical trial approval listing PureGen as "Biological: PureGen Osteoprogenitor Cell Allograft".

a. By continuing to ship and sell PureGen for off label uses in humans following the warning by the FDA that continuing to do so was in violation of federal law, Alphatec and Parcell proximately and actually caused the harm suffered by Relators and by similar patients.

b. Despite the approval for the clinical trial of PureGen which limited enrollment to 50 patients, Alphatec advertised in its 2012 Annual Report (Page 26) that PureGen has been implanted into over 3,500 patients.

29. Alphatec stated Parcell agreed with their assessment that PureGen is a tissue product and that they had stopped shipping PureGen in February of 2013.

30. Upon the following information and belief, Alphatec and Parcell are still shipping the product PureGen as part of their off label marketing:

a. PureGen has been implanted into certain of the Relators and presumably other patients since February 2013.

31. Alphatec and Parcell engaged in a fraudulent course of conduct designed to maximize their revenues from PureGen regardless of whether the product would eventually be allowed to remain on the market.

32. In furtherance of the fraudulent course of conduct, Alphatec and Parcell utilized false statements and claims made by themselves and by biased physicians and employed a scheme that involved PureGen.

33. Alphatec and Parcell marketed the PureGen product 1) by improper kickback payments for each use of the device and for marketing efforts sometimes disguised as legitimate payments for other services; 2) by sponsoring research, articles, presentations, and other communications without disclosing the sponsorship, control, or bias of these communications which presented the PureGen device as having less severe side effects than were known, which represented the device could be safely and effectively used without a safety and effectiveness review of the FDA, and which were intended to compromise the independent medical judgment of medical service providers in recommending and using PureGen off label; 3) by co-opting physicians in part by making consulting payments and other remuneration to surgeon customers to experimentally use the device PureGen on patients and report the results in a biased manner to conceal risks while overstating the effectiveness of the device and not revealing their bias or the control of Alphatec and Parcell over the reported results; 4) by encouraging other physicians to use the device off label in their patients by the misrepresentations of safety and effectiveness and by bolstering these misrepresentations by failing to disclose bias of the entity making the misstatement; 5) by preventing patients from being informed of the nature of the surgery they were being asked to give consent for by concealing known

risks from surgeons and by improperly influencing the physician's decision to use PureGen by direct payments and concealed kickbacks and not disclosing the financial ties between manufacturer and physician to the patient.

34. Doctor Atiq Abubakar Durrani used the product Puregen in his capacity as a medical doctor.
35. Defendants knowingly provided Puregen to Dr. Durrani.
36. A representative from Alphatec Spine was in the operating room during medical procedures per the Nursing Intraop Records.
37. A representative from Alphatec Spine was in the operating room during medical procedures even when the Nursing Intraop Records do not indicate so.
38. Dr. Durrani is a consultant for Defendant corporations.
39. Dr. Durrani has an ownership stake in the Defendant corporations.
40. Dr. Durrani provided Puregen to both patients who required surgery and those who did not require surgery.
41. Dr. Durrani performed unnecessary surgeries using Puregen on his patients.
42. Defendants knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim.
43. Defendants knowingly presented, or caused to be presented, a fraudulent claim for payment or approval.
44. Defendants authorized and ratified all of the violations of the False Claims Act committed by its various officers, agents, and employees.
45. The Relators have filed or will soon file individual medical malpractice actions against the Defendants; the discovery from these actions will be used to support the allegations

contained herein and delivered to the Government as supplements to the initial disclosure statement.

46. Alphatec made comparisons of PureGen to the Allograft procedure but did not conduct or report a study comparing the two. This comparison did not disclose any risks of PureGen and represented the outcome as superior to allograft. These representations were again made at the North American Spine Society Annual Meeting 2010. See Alphatec press release October 5, 2010, quoted by globenewswire.com, attached as Exhibit A. See also Alphatec Holdings Inc. 10k 2012 at page 7, excerpt attached as Exhibit B.

47. In the first quarter of 2011, Alphatec Spine attributed part of its 40.9% increase in revenue to the PureGen product. See Becker's Spine Review, Alphatec Spine Reports $49.7M in Q1 Revenue, 40.9% Increase, May 5, 2011, attached as Exhibit C.

48. In November of 2010, Puregen was listed in OR Manager magazine (Vol 26, No 11, Page 11, attached as Exhibit D) as a stem cell-based autograft substitute available on the market, implying safety and effectiveness for that use.

49. For years, Alphatec and Parcell have sought to replace the ideal bone graft, autologous bone graft, as the recognized standard in spinal fusions. They did this through false statements, false claims, misrepresenting and concealing risks, misstating the advantages, if any, of PureGen over autograft, and through cooperation of the other members of a fraudulent enterprise, as described in this Complaint, using federal funds to do so.

50. Defendants misappropriated Federal funds intended to provide medical treatment to beneficiaries for research and development expenses, illegal marketing, and fraudulent sales of PureGen.

51. Since developing PureGen, Alphatec and Parcell have engaged in an aggressive

marketing campaign with blatant disregard to regulatory requirements, effectiveness of the product for the uses it was/is being marketed for, the safety for the uses it was/is being marketed for, and the standards usually held by the scientific community. These marketing efforts relied on fraud, deceit, and false statements and resulted in false claims for Federal funds being made for the use of PureGen in unapproved ways on patients who were not properly informed of the risks.

52. The participants in the fraudulent enterprise failed to report clear conflicts of interest on the part of those holding positions of trust in the medical community and over patients as part of the fraudulent enterprise. Unchecked by peer review and other industry safeguards which had been compromised by Alphatec and Parcell through illegal payments and co-opting, this fraudulent scheme went undetected until after the harm to the Relators had occurred. The Defendants have been able to accomplish their goals through this scheme.

53. Alphatec characterizes and labels the removal of PureGen from the market as voluntary, however, it was an illegally marketed product from the time it entered the market. PureGen has always been officially described as a biologic and never as a tissue. Alphatec knowingly and intentionally illegally marketed PureGen for use in patients like the Relators, and for payment from Federal benefits programs through the submission of false claims.

54. According to Alphatec, removal of PureGen from the market has cost them $2.4M in six months.

55. In violation of the Common Rule (45 C.F.R. 46), and in furtherance of the scheme to feign avoidance of the anti-kickback statutes, the Defendants experimented on their patients, including Relators, by using PureGen without advising the patients or getting

their informed consent. The purpose of the mechanism was to both conceal kickbacks and improperly gain consent to the experimental surgeries.

56. The surgeries served as a source of information which could then serve as the basis for compensation for the real contribution: performing the surgeries without regard for patient health and as a biased research project.

57. The lack of informed consent allowed the Defendants to conduct the experimental surgeries on patients and release the skewed results without having other researchers or protocol second-guess them. These "successful" off label surgeries would then be used to obtain approval in the first place and as a basis for expanding approval later on. Alphatec mentions that over 3,500 successful, off label surgeries had been completed by the time they "voluntarily" removed PureGen from the market, with no adverse side effects. That research was conducted using Federal funds and unknowing and unwilling participants.

58. The fraudulently Federally-funded research surgeries were and are significant to the scheme.

59. The Defendants concealed serious medical risks and complications to increase profits, specifically omitting that PureGen would be used, omitting that the effectiveness and safety of PureGen had not been determined at that time, representing that the surgery they would undergo was similar to an autograft or allograft procedure, and omitting any other risk factors known by Alphatec and Parcell at that time.

60. In order to funnel payments to physicians for participating in the scheme while avoiding detection under the anti-kickback statutes, Alphatec and Parcell used sham agreements for patents or other services, physician-owned distributorships, travel and perks, payments to wholly owned enterprises legally organized by the other Defendants, and

other sham agreements. To further conceal these payments, they were mingled together with other payments and no itemization to allow the amounts to be readily determined.

61. The Defendants participated in the paying, receiving, and laundering of kickbacks for their own direct gain as individuals and to induce the purchase of PureGen.

62. Compliance with the Anti-Kickback statutes is a condition of receiving payment from a Federally-funded healthcare program. The Anti-Kickback Statute prohibits the payment and receipt of kickbacks in return for either procuring or recommending the procurement of a good, facility, or item to be paid in whole or in part by a federal healthcare program. 42 U.S.C. §1320a-7b(b).

63. Through the kickback scheme as set forth herein, the Defendants knowingly or with deliberate indifference or reckless disregard for truth or falsity submitted directly or caused other healthcare providers to present false or fraudulent claims for payment to federal healthcare programs.

64. In making claims for services and product reimbursement, the Defendants, and each of them individually, represented compliance with a material condition of payment that was not in fact met, that being that the treatment rendered did not violate the anti-kickback statute. The Defendants also violated conditions for payment and reimbursement by representing surgeries as medically necessary which were not. The Defendants also failed to meet conditions for payment and reimbursement by concealing the use of the biologic drug PureGen in the billing and by failing to apply for and receive precertification for the experimental use of the drug. Thus each of the claims made by Defendants was false or fraudulent in at least one material way.

65. The Defendants made and caused to be made additional false statements and

certifications resulting in violations of the False Claims Act as follows, but not limited to:

a. The Defendants together and individually knew that the surgeries using PureGen were not approved by the FDA (off label) and were being performed without the consent and knowledge of the patients;

b. The Defendants combined and individually knew the surgeries were not being performed for the health of the patient and rather the surgeries were being performed to 1) obtain and expand the approval of PureGen, and 2) provide a purported basis for avoiding the anti-kickback laws, which itself constitutes fraud and material misrepresentation;

c. The Defendants and each of them knew that the financial relationships of the Defendants were not being disclosed to the patients, or that these relationships resulted in the significant receipt of sums by the Defendants;

d. The Defendants and each of them individually knew of material risks or were intentionally ignorant of material risks associated with PureGen, and each knew the patients had not been informed of either known risks or that the PureGen drug was at a stage too early to determine the material risks associated with its use;

e. The Defendants and each of them knew the surgeries were experimental in nature and the patients had not been informed of the experimental nature, and that no safeguards had been put in place to ensure they had provided informed consent for experimental surgery or to be used in a clinical trial or to be used in a study using PureGen, and that the patients had not had opportunity to refuse such experimental treatment or involvement;

f. Defendants and each of them therefore knew the forms included in each patient's medical records documenting informed consent were false;

g. The Defendants and each of them knew that presenting these forms was a condition precedent to payment for Medicare patients, in that payments would not have been made by the United States had the Centers for Medicare and Medicaid Services (CMS) known that patients were being subjected to unapproved clinical trials, studies, and other experiments without their informed consent;

h. The Defendants and each of them knew that these false documents had been created, were being maintained uncorrected, and were being presented for payment as a material part of each claim for payment and reimbursement from the United States for Medicare patients and/or informed consent and a representation that informed consent had been given by the patient was a necessary part of such payments;

i. The presentment for payment by Medicare of documents falsely claiming that patient consent had been given was the natural, ordinary, and reasonable consequence of their common scheme. Each Defendant knew that such conduct was occurring because it was a beneficial and/or necessary component of their scheme.

66. Additionally, the Defendants made and caused to be made additional false statements and certifications resulting in violations of the False Claims Act in that the information submitted to the CMS, including CPT coders and modifier information contained on the Health Insurance Claim Forms, including those of Relators, was materially false and misleading in that absent those false representations payment would not have been made.

67. West Chester Hospital, Journey Lite, and the Center for Advanced Spine Technologies

(the Location Defendants) knowingly created false medical records, bills, and cost reports that included charges for off label uses of PureGen, which resulted in inflated outlier payments to be paid by the government; or in the alternative, the other Defendants caused the Location Defendants to make such false cost reports.

68. This *qui tam* action is begin brought to recover all funds paid through false or fraudulent claims conspired for, and presented, by the Defendants upon Medicare and Medicaid programs, as well as all other government programs that have been affected. This Complaint is being brought by Relators for disgorgement of gross receipts, or profits, and other damages for that very reason; because Alphatec and Parcell have engaged in a thorough and lengthy fraudulent enterprise employing its physician agents and cooperative Locations to simply increase profits.

IDENTIFICATION OF REALTORS AND SPECIFIC EXAMPLES

69. On January 27, 2012, Dr. Durrani performed an unnecessary surgery on Julie Martin. The improper preoperative diagnosis was 1. Degenerative spondylolithesis L5-S1, 2. Degenerative spinal stenosis L5-S1, and 3. Lumbar radiculopathy L5. On or around December 17th, 2011, Dr. Durrani exclaimed "were you in an accident?" while reviewing Martin's x-ray with her. This statement was an exaggeration and intentional misstatement intended to obtain Martin's consent to surgery that was not indicated by that x-ray or subsequent radiology. Based on Dr. Durrani's deception and false diagnosis, Martin consented to the medically unnecessary surgery. The procedure was 1) L5-S1 transforaminal lumbar disketomy left side, 2) transforaminal lumbar interbody fusion L5-S1 using autograft and allograft, 3) Placement of TLIF cage L5-S1 (Trans1), 4) Posterior spinal instrumentation (DePuy), and 5) Posterior spinal fusion using auto and allograft

L5-S1. In fact, Dr. Durrani used PureGen in an experimental manner without disclosure in his operative report, to the patient beforehand, or to the insurer on the bill. There was no lot number or serial number recorded for the PureGen that was used in violation of any applicable tracking requirement, the catalog number was 67010-050, and the expiration date was 2/25/2012.

70. On February 11, 2013, Joetta Nafe underwent surgery with Dr. Durrani using PureGen. The preoperative diagnosis was 1) L5-S1 degenerative spinal stenosis, 2) L5-S1 degenerative spondylolisthesis, 3) L5-S1 Foraminal stenosis, and 4) L5 & S1 lumbar Radiculopathy with sensory neuropathy. The surgery was 1) L5-S1 lumbar laminectomy, 2) L5-S1 trans-foraminal lumbar interbody fusion using auto and allograft, 3) L5-S1 TLIF cage placement, 4) Posterior spinal instrumentation L5-S1, and 5) Posterior spinal fusion using auto and allograft L5-S1. PureGen is listed as an implant. Lot number is listed as N/A. Serial number is AS30005783. No catalog number or expiration date is listed.

71. On August 25, 2010, Dr. Durrani performed surgery on Carol Ross. The preoperative diagnosis was cervical spinal stenosis at C4-C5-C6-C7-T1. The procedures were cervical spinal instrumentation from C4 through T1, cervical spinal fusion from C4through T1, Cervical laminectomy from C4 through T1, and cervical foraminotomy from C4 through T1. Upon information and belief, this first surgery was unnecessary: two other doctors who reviewed the radiology at the time determined Ross' spine was stable and noted no significant defects. On December 7, 2012, Dr. Durrani and/or Dr. Shanti (Dr. Shanti is believed to have been performing surgeries and charging for them under Dr. Durrani's provider number with full cooperation and knowledge of Dr. Durrani and the Location

Defendants, and Dr. Shanti is listed as the author of the progress notes) used PureGen in a surgery on Carol Ross. The serial number was AS30001163, the catalog number was 67010-050, the lot number and expiration date are not found in the records currently available. The preoperative diagnosis was "large disc herniation causing severe central and foraminal stenosis." The procedure was 1) anterior cervical discectomy C7-T1, 2) anterior cervical fusion using allograft C7-T1, 3) placement of an anterior interbody cage C7-T1, and 4) anterior cervical instrumentation C7-T1. Charges for Puregen were submitted to Humana as a result of this surgery.

72. Dr. Durrani performed 2 surgeries on Joseph Schimmel and used Puregen and charged for an "Allograft Puregen" line item on the bill in each surgery. The dates of the surgeries were on or around August 15, 2012 and September 26, 2012. These bills were submitted to Medicare A and B for payment.

73. On December 26, 2012, Dr. Durrani performed surgery on Dana Setters using PureGen. The serial number was either SNAS30001482 or NAS30001482. There was no expiration date, lot number, or catalog number in the medical records provided by West Chester. The preoperative diagnosis was C1-C2 rotary instability, EDS (Ehlers-Danlos Syndrome), and Cervico-Medullary syndrome. The procedure performed was C1-C2 posterior spinal instrumentation (C1 isthmus screw and C2 pedicle screws) and posterior spinal fusion C1-C2 with autograft and allograft. PureGen was reported as allograft. Durrani reported and charged for 4 screws and 2 rods, however an MRI revealed that only 2 screws and 1 rod were implanted.

74. On January 20, 2012, Dr. Durrani performed surgery on Daniel Webber. Humana denied payment in part for undetermined equipment and supplies used in the surgery because an

approved IND and a biologics license were lacking and thus the surgery was experimental. These supplies were valued at $9,438.98. Upon information and belief the supplies were PureGen: Alphatec is listed as the supplier of the instrumentation and cage(s) used in the surgery, and the denial of coverage describes the supplies as a biologics.

75. Dorothy Rose - Dr. Durrani, or Dr. Shanti using Dr. Durrani's provider number and with Dr. Durrani signing the operative report and taking other steps necessary to fraudulently represent that he had performed the surgery, all with full knowledge and cooperation of West Chester, performed 2 surgeries on Dorothy Rose. Upon information and belief the first surgery was medically unnecessary, unsupported by radiology, and unsupported by other factors such as age and activity level: a non-treating nurse has opined that based on the medical records the surgery was likely unnecessary; Dr. Durrani's diagnoses based on the radiology directly contradicts the radiologist or is unrelated to the radiologist's interpretation; Dr. Durrani recommended surgery without additional radiology, and did so on the first office visit. In at least one of the surgeries, PureGen was used. The intraoperative record for the second surgery shows PureGen used on April 16, 2012 in Dorothy Rose during a Cervical four-five, cervical five-six anterior cervical discectomy and fusion based on the preoperative diagnosis: degenerative disc disease cervical, spinal stenosis cervical. The PureGen was catalog number 67010-010, serial number AS00000441, Lot number 101124-C05, expiration date 04/27/2012. Based on information and belief, the first surgery on August 8, 2011 was performed by Dr. Shanti and billed under Dr. Durrani: The preop record shows Dr. Durrani as the surgeon, but the intraoperative report shows Dr. Shanti as the primary surgeon; Dr. Durrani is listed as

being in the room for 6 total minutes during the surgery, all of which occurred after Dr. Shanti left the room. These surgeries were charged to Humana, Medicare, OPERS Humana Medicare Advantage or some combination of those plans or in addition to other government benefit programs.

76. On July 23, 2012, Dr. Durrani performed surgery on Timothy Marshall and used PureGen. The catalog number was 67010-010, lot number field is blank, serial number AS700005727, and expiration date August 18, 2012. The preoperative diagnosis was Degenerative disc disease lumbar, spinal stenosis lumbar. The Procedure was lumbar 1-2, lumbar 2-3, lumbar 3-4, lumbar 4-5, laminectomy, posterior spinal fusion. Upon information and belief the surgery was not medically indicated: Mr. Marshall weighed 422 lbs at the time Dr. Durrani recommended surgery, while Dr. Durrani knew the risks were significantly higher for an overweight patient with Mr. Marshall's other medical conditions including diabetes, hypertension, hyperlipidemia, sleep apnea, morbid obesity, coronary artery disease; another doctor had previously – sometime in 2008 – told Mr. Marshall that back surgery was not safe given his size.

77. Dr. Durrani performed surgery on Mary Ravenscraft on February 15, 2013 using PureGen: Dr. Durrani's operative note states that he used PureGen Stem Cells however the implant is not itemized on the corresponding implant log. Upon the same information and belief, Dr. Durrani concealed the use of PureGen when he submitted a claim, or caused a claim to be submitted, for the surgery; and such concealment was his pattern and practice. The preoperative diagnosis was lumbar spinal stenosis L5-S1 right, lumbar degenerative spondylolisthesis L5-S1 right, lumbar bilateral foraminal stenosis L5-S1 right, lumbar radiculopathy L5. The

procedure was transforaminal lumbar interbody discectomy L5-S1, transforaminal lumbar interbody fusion L5-S1 using auto and allograft, placement of TLIF cage, posterior spinal fusion L5-S1 using auto and allograft, posterior spinal instrumentation L5-S1.

78. On 06/29/2012 Donna Rister with a pre-op diagnosis of; herniated disc cervical, degenerative disc disease cervical, and spinal stenosis cervical, presented to Westchester Medical Center for the following procedure; Cervical 5-6, Anterior Cervical Discectomy and Fusion performed on her by Dr. Abubakar Durrani. During this surgery Miss Rister received 1 implant of 0.5ml Puregen Allograft into the cervical spine. The implant was manufactured by Alphatec Spine and was represented by Tom Blank Alphatec Spine Sales Representative. Tom Blank was present in the OR for the procedure. The unit implanted was catalog # 67010-010, Lot number, 110406-C03, Expiration Date 07/02/2012, a serial # was not recorded.

79. On 8/16/2012 Donna Good with a pre-op diagnosis of lumbar spinal stenosis, presented to Westchester Medical Center for the following procedure; Lumbar 4-5 Direct Lateral Interbody Fusion, Lumbar 4-5 Posterior Instrumented Spinal Fusion, Lumbar 4-5 Laminectomy. Dr. Neal Shanti performed this procedure. During the procedure Miss Good received 1 implant of Allograft Puregen Med 1.0ml into the Lumbar Spine 4-5. The implant was manufactured by Alpha Scientific and represented by Tom Blank Alphatec Spine Sales Representative. Tom Blank was present in the OR for the procedure. The unit implanted was catalog number #67010-050, Lot Number, 110602-C01, Expiration Date

08/31/2012, Serial Number #AS30003860. Comment recorded: Verified with Dr. Shanti prior to opening.

80. On 08/22/2012 Teresa Mcmillen with a pre-op diagnosis of Kyphosis, presented to Westchester Medical Center for the following procedure; Thoracic4-5, Thoracic 5-6, Thoracic 6-7, Thoracic 7-8, Thoracic8-9, Thoracic 9-10, Thoracic 11-12, Thoracic 12 – Lumbar 1, Lumbar 1-2 Posterior Spinal Fusion, Thoracic 7-8, Thoracic 8-9, Thoracic 9-10 Osteomies. Dr. Abubakar Durrani performed this procedure. During the procedure Miss McMillen received 1 implant of Allograft Puregen LG 2.0ml into the Thoracic Spine. The implant was manufactured by Alphatec Scientific and represented by Tom Blank Alphatec Spine Sales Representative. Tom Blank was present in the OR for the procedure. The unit implanted was catalog number #67010-100, Lot Number not entered, Expiration Date 09/18/2016, Serial Number #AS70005666.

81. On 03/26/2012/ George Arnold with a pre-op diagnosis of Herniated Disc cervical, Spinal Stenosis Cervical, presented to Westchester Medical for the following procedure; Cervical 4-5, Cervical 5-6 Anterior Cervical Discectomy and fusion. . Dr. Abubakar Durrani performed this procedure. During the procedure Mr. Arnold received 1 implant of Allograft Puregen SM 0.5ml into the Cervical Spine. The implant was manufactured by Alphatec Scientific and represented by Tom Blank Alphatec Spine Sales Representative. Tom Blank was present in the OR for the procedure. The unit implanted was catalog number #67010-100, Lot Number not entered, Expiration Date 04/19/2012, Serial Number #AS00000778.

82. On 07/27/2012 Carolyn Dotson with a pre-op diagnosis of Lumbar Stenosis, presented to Westchester Medical Center for the following procedure; Right Lumbar 4-5 Transforaminal Lumbar Interbody Fusion, Posterior Spinal Fusion, Bilateral Lumbar 4-5, Lumbar 5-Sacral 1 Foraminotomy and Decompression; Dural Repair. Dr. Abubakar Durrani performed this procedure. During the procedure Mr. Arnold received 1 implant of Allograft Puregen MED 1.0ml into the Spine. The implant was manufactured by Alphatec Scientific and represented by Tom Blank Alphatec Spine Sales Representative. Tom Blank was present in the OR for the procedure. The unit implanted was catalog number #67010-050, Lot Number AS3000005361, Expiration Date 08/22/2012, Serial Number # not entered. However, the lot number entered follows the number sequence that is used for the implant serial number.

83. On 06/08/2012 Laura Batsche with a pre-op diagnosis of: none provided on intraoperative report, presented to Westchester Medical Center for the following procedure; Anterior Cervical Discectomy and Fusion Cervical 5-6, Cervical 6-7. . Dr. Abubakar Durrani performed this procedure. During the procedure Miss. Batsche received 1 implant of Allograft Puregen SM 0.5ml into the Cervical Spine. The implant was manufactured by Alphatec Scientific and represented by Tom Blank Alphatec Spine Sales Representative. Tom Blank was present in the OR for the procedure. The unit implanted was catalog number #67010-010, Lot Number AS00000931, Expiration Date 06/18/2012, Serial Number # not entered. However, the lot number entered follows the number sequence that is used for the implant serial number. Laura Batsche's operative report was destroyed and/or

wrongfully kept from Realtor by the Defendants in an effort to cover up the use of Puregen in her surgery.

84. On 12/07/2012 Randall Brewer with a pre-op diagnosis of L5-S1 Degenerative Spinal Stenosis, L5-S1 Degenerative Spondylolisthesis, L5-S1 Foraminal Stenosis, and L5-S1 Lumbar radiculopathy with sensory neuropathy, presented to Westchester Medical Center for the following procedure; L5-S1 Lumbar Laminectomy, L5-S1 Trans-foraminal lumbar interbody fusion using auto & allograft, L5-S1 Cage placement, posterior spinal instrumentation L5-S1, and posterior spinal fusion using auto &allograft L5-S1. . Dr. Abubakar Durrani performed this procedure. During the procedure Mr. Brewer received 1 implant of Allograft Puregen MED 1.0ml – LOG9288. The implant was manufactured by Alpha Scientific Corp. No sales representative listed. Lot # AS300001429.

85. On 08/17/2012 Kelly Hennessy with a pre-op diagnosis of Herniated Disc Cervical, Herniated Disc Thoracic presented to Westchester Medical Center for the following procedure; Thoracic 2-3, Thoracic 3-4, thoracic 4-5, Thoracic 5-6 extension of Fusion, Posterior Spinal Fusion, Thoracic 2-Thoracic 6. Dr. Abubakar Durrani performed this procedure. During the procedure Miss Hennessy received 1 implant of Allograft Puregen MED 1.0ml into the Thoracic Spine. The implant was manufactured by Alphatec Spine and represented by Tom Blank Alphatec Spine Sales Representative. Tom Blank was present in the OR for the procedure. The unit implanted was catalog number #67010-050, Lot Number 116257-634, Expiration Date 05/24/2014, Serial Number # not entered.

86. William Hayes - On 06/06/12, Durrani performed a medically unnecessary DLIF

spine surgery from L4-S1 on William Hayes and improperly used Puregen at West Chester Hospital and UC Health. Alpha Spine sales representative Tom Blank was present during the surgery. The Puregen that was used expired 23 days later on 07/13/12; The Puregen used was a 1.0 ml unit, serial number as30001413, lot number was not recorded, catalog no.: 67010-050.

87. On 02/22/13, Durrani used Puregen on Tammy Jones during a medically unnecessary TLIF lumbar spine surgery from L3-L5 at Journey Lite of Cincinnati, LLC. Alpha Spine sales representative Tom Blank was present during the surgery. Immediately following the surgery, the hardware failed and had to be revised in a second surgery that same day.

88. On 07/30/12, Durrani used Puregen on Joann Frazier at West Chester Hospital and UC Health during an medically unnecessary DLIF instrumented spine fusion surgery from L4-L5. Alpha Spine sales representative Tom Blank was present during the surgery. The Puregen was a 1.0 ml size, Catalog No.: 67010-050, the serial number was not recorded by the Defendants, the expiration date was 08/22/12, Lot No.: as30005463.

89. On 02/13/2013 Sandra Dennis with a pre-op diagnosis of C1-C2 Rotary Instability, C1-C2 Arthrosis, Cervico –Medullary Syndrome, presented to UHC Westchester Hospital for the following procedure; C1-C2 Posterior Spinal Implementation (C1 Isthmus Screw, C2 Pedicle Screws, C3 Lateral Mass Screws). Posterior Spinal Fusion with Autograft and Allograft, Right sied Cervical Hemilaminectomy and Foraminotomy. Dr. Abubakar Durrani performed this medically unnecessary procedure. During the procedure Sandra Dennis

received 1 implant of Allograft Puregen MED 1.0ml into the Cervical Spine. The implant was manufactured by Alpha Scientific Corp. The unit implanted was catalog number – not entered, Lot Number not entered, Expiration Date not entered, Serial Number # As3000547. It is believed this Puregen unit was fully expired when it was improperly used on Mrs. Dennis.

COUNT I

VIOLATIONS OF 31 USC § 3729, et seq.

90. Plaintiffs/Relators restate, replead, and incorporate all previous paragraphs as if restated herein.

91. This Count is brought by Plaintiffs/Relators in the name of the United States under the Qui Tam provisions of 31 U.S.C. § 3730 for Defendant's violations of 31 U.S.C. 31§ 3729.

92. Defendants acting as individuals and/or through their officers, employees, agents, adjusters, and independent contractors, and in concert through their fraudulent enterprise and civil conspiracy, knowingly made, used, or caused to be made or caused to be used, false records in support of false claims.

93. Those false records included, but were not limited to: 1) false records generated for reimbursement of medical services for surgeries and related care; 2) false records generated for reimbursement of Puregen and other products containing PureGen, if they exist; 3) false records generated to conceal the fraudulent scheme to maintain the appearance of compliance with Anti-Kickback Statutes, laws, and regulations; 4) false records generated in order to launder money in an effort to facilitate the fraudulent scheme to maintain the appearance of compliance with Anti-Kickback laws and

regulations; 5) and others.

94. Defendants submitted or caused to be submitted these false records and statements in order to get false or fraudulent claims approved or paid by the Government, and/or to avoid further payments, penalties, or obligations under the reverse false claims provisions of 31 U.S.C. §3729(a)(7).

95. The amounts of the false or fraudulent claims to the United States were material.

96. The United States Government and the public have been damaged as a result of Defendant's violations of the False Claims Act.

97. WHEREFORE, Relators demand judgment against the Defendants jointly and severally in the amount of three times the false or fraudulent charges, or overcharges, submitted for payment to the United States Government, for a civil penalty against the Defendants each jointly and severally in an amount between Five Thousand, Five Hundred Dollars ($5,500) and Eleven Thousand Dollars ($11,000) for each violation of 31 U.S.C. §3729, et seq., or such maximum amount as allowed by law; for the maximum amount allowed to the Qui Tam Plaintiffs/Relators under 31 U.S.C. §3730(d) of the False Claims Act; for treble damages or any other applicable provision of law, including any alternate remedy provisions; for its court costs and reasonable attorney's fees at prevailing rates; for expenses; for exemplary damages and for such other and further relief as this Court deems meet, just, and proper.

COUNT II

VIOLATIONS OF 31 USC §3729(a)(2)

98. Plaintiffs/Relators restate, replead, and incorporate all previous paragraphs as if restated herein, and allege violations of 31 U.S.C. §3729(a)(2).

99. WHEREFORE, Relators demand judgment against the Defendants jointly and severally in the amount of three times the false or fraudulent charges, or overcharges, submitted for payment to the United States Government, for a civil penalty against the Defendants each jointly and severally in an amount between Five Thousand, Five Hundred Dollars ($5,500) and Eleven Thousand Dollars ($11,000) for each violation of 31 U.S.C. §3729, et seq., or such maximum amount as allowed by law; for the maximum amount allowed to the Qui Tam Plaintiffs/Relators under 31 U.S.C. §3730(d) of the False Claims Act; for treble damages or any other applicable provision of law, including any alternate remedy provisions; for its court costs and reasonable attorney's fees at prevailing rates; for expenses; for exemplary damages and for such other and further relief as this Court deems meet, just, and proper.

COUNT III

VIOLATIONS OF 31 USC §3729(a)(3)

100. Plaintiffs/Relators restate, replead, and incorporate all previous paragraphs as if restated herein, and allege violations of 31 U.S.C. §3729(a)(3).

101. WHEREFORE, Relators demand judgment against the Defendants jointly and severally in the amount of three times the false or fraudulent charges, or overcharges, submitted for payment to the United States Government, for a civil penalty against the Defendants each jointly and severally in an amount between Five Thousand, Five Hundred Dollars ($5,500) and Eleven Thousand Dollars ($11,000) for each violation of 31 U.S.C. §3729, et seq., or such maximum amount as allowed by law; for the maximum amount allowed to the Qui Tam Plaintiffs/Relators under 31 U.S.C. §3730(d) of the False Claims Act; for treble damages or any other applicable provision of law, including any

alternate remedy provisions; for its court costs and reasonable attorney's fees at prevailing rates; for expenses; for exemplary damages and for such other and further relief as this Court deems meet, just, and proper.

COUNT IV

VIOLATIONS OF 42 USC §1320a-7b(b)

102. Plaintiffs/Relators restate, replead, and incorporate all previous paragraphs as if restated herein, and allege violations of 42 U.S.C. §1320a-7b(b), and other Anti-Kickback Statutes.

103. WHEREFORE, Relators demand judgment against the Defendants jointly and severally in the amount of three times the false or fraudulent charges, or overcharges, submitted for payment to the United States Government, for a civil penalty for each violation of 42 U.S.C. §1320a-7b(b), the Anti-Kickback Statute; for treble damages or any other applicable provision of law, including any alternate remedy provisions; for its court costs and reasonable attorney's fees at prevailing rates; for expenses; for exemplary damages and for such other and further relief as this Court deems meet, just, and proper.

COUNT V

CIVIL PENALTIES OR AWARDS ARISING FROM CRIMINAL CONDUCT

104. Plaintiffs/Relators restate, replead, and incorporate all previous paragraphs as if restated herein, and allege violations of various civil codes providing for all civil penalties or awards allowed relative to any criminal conduct of the Defendants, if any, including but not limited to those relative to 18 U.S.C §§1341, 1343, 1956, 1957, and 2314 covering mail fraud, wire fraud, money laundering, use of dirty money, and travel to effect the scheme, to effectuate the fraudulent scheme.

105. WHEREFORE, Relators demand judgment against the Defendants jointly and severally in the amount of three times the false or fraudulent charges, or overcharges, submitted for payment to the United States Government, for a civil penalty against the Defendants each jointly and severally in an amount between Five Thousand, Five Hundred Dollars ($5,500) and Eleven Thousand Dollars ($11,000) for each violation of 31 U.S.C. §3729, et seq., or such maximum amount as allowed by law; for the maximum amount allowed to the Qui Tam Plaintiffs/Relators under 31 U.S.C. §3730(d) of the False Claims Act; for treble damages or any other applicable provision of law, including any alternate remedy provisions; for its court costs and reasonable attorney's fees at prevailing rates; for expenses; for exemplary damages and for such other and further relief as this Court deems meet, just, and proper.

COUNT VI

VIOLATIONS OF 45 CFR 46, et seq.

106. Plaintiffs/Relators restate, replead, and incorporate all previous paragraphs as if restated herein, and allege violations of various federal statutes known as the "Common Rule," located at 45 CFR 46, et seq., or elsewhere, covering the conduct of medical research on human subjects with the support of federal funds.

107. WHEREFORE, Relators demand judgment against the Defendants jointly and severally in the fullest amount allowed by law, for all civil penalties or awards allowed for each violation of the Common Rule; for treble damages or any other applicable provision of law, including any alternate remedy provisions; for its court costs and reasonable attorney's fees at prevailing rates; for expenses; for exemplary damages and for such other and further relief as this Court deems meet, just, and proper.

COUNT VII

UNJUST ENRICHMENT, EQUITABLE, AND GENERAL RELIEF

108. Plaintiffs/Relators restate, replead, and incorporate all previous paragraphs as if restated herein, and allege the Defendants' conduct, if allowed, would constitute unjust enrichment and falls under the equitable powers of the Court to address and remedy.

109. WHEREFORE, Relators further demand judgment against the Defendants jointly and severally for a fair and reasonable amount as determined by a jury, for treble damages, civil penalties, disgorgement of gross receipts or profits, the imposition of a constructive trust, court costs and reasonable attorney's fees at prevailing rates, expenses, exemplary damages and all other applicable remedies, and for such other and further relief as this Court deems meet, just, and proper.

PRAYER FOR RELIEF

WHEREFORE, that as a direct and proximate result of the false claims, acts, and omissions stated herein, the Relators, the United States Government, the Commonwealth of Kentucky, the State of Ohio, and the public interest have been financially damaged and defrauded as a result of Defendants in violation of the false claims act and other applicable laws. Relators request relief as follows:

A. Judgment against Defendants on all claims;

B. A jury trial on all issues so triable;

C. Awarding treble damages or any other remedy or provision of law for each false or fraudulent charge, or overcharge, submitted for payment to the United States Government;

D. Awarding civil penalties against the Defendants each jointly and severally in an amount between five thousand five hundred dollars ($5,500) and eleven thousand dollars ($11,000) for each violation of 31 U.S.C. § 3729, et seq.; of 42 U.S.C. § 1320a-7b(b), and other Anti-Kickback Statutes; of 45 C.F.R. 46, et seq.; or such other maximum amount allowed by law;

E. Awarding restitution and disgorgement of gross receipts or profits;

F. Awarding declaratory and injunctive relief as permitted by law or equity, as necessary to protect the public health an welfare;

G. Awarding exemplary/punitive damages;

H. Awarding attorney's fees;

I. Awarding costs associated with disbursement of this action;

J. Awarding a proportionate share of any alternate remedy obtained pursuant to 31 U.S.C. §3730(c)(5);

K. Awarding interest;

L. Affording a hearing prior to settlement or dismissal; and

M. Providing such further relief as may be just and proper.

AND if Plaintiffs/Relators have prayed for incorrect or insufficient relief, they request that the prayer for relief be amended to allow for such other or further relief, both legal and equitable, as this Court deems meet, just, and proper in the premises.

Respectfully Submitted,

Eric C. Deters, Esq. (38050)
ERIC C. DETERS & PARTNERS, PSC

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Independence, Kentucky 41051
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JURY DEMAND

Plaintiffs respectfully request a trial by jury.

Eric Deters

CERTIFICATE OF SERVICE

The foregoing document was filed this 23rd day of August 2013. Notice of filing will be sent to the Attorney General in Washington, D.C. by mail and to the US Attorney's Office for the Southern District of Ohio by hand delivery as soon as a file stamped copy is received.

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